K002605

NOV 2 0 2000

3. Summary of Safety and Effectiveness Information:

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Bonnie Smith
Device Name:	Synthes (USA) 4.0/2.5 mm Self-Drilling Schanz Screw
Device Classification:	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener.
Predicate Device:	Synthes (USA) 1.6 mm Kirschner Wire
Description of Device:	Synthes 4.0/2.5 mm Self-Drilling Schanz Screw is a solid screw with a dual-fluted, twist drill tip and smooth shank. The Schanz screw is 80 mm in length.
Indications:	Synthes 4.0/2.5 mm Self-Drilling Schanz Screw is an external fixation component intended for use in the metacarpals to reduce and stabilize fractures of the hand and wrist.
Material:	Available in Stainless Steel or Commercially Pure Titanium

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Bonnie J. Smith, RAC
Senior Regulatory Affairs Associate
Synthes (USA)
P.O. Box 1766
1690 Russell Road
Paoli, PA 19301

APR 5 2002

Re: K002605
Trade/Device Name: 4.0/2.5 MM Self-Drilling Schanz Screw
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDW
Dated: August 18, 2000
Received: August 22, 2000

Dear Ms. Smith:

This letter corrects our substantially equivalent letter of November 20, 2000 regarding the company name.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

2. Indications for Use

510(k) Number (if known): _____

Device Name: Synthes (USA) 4.0/2.5 mm Self-Drilling Schanz Screw

Indications for Use: Synthes 4.0/2.5 mm Self-Drilling Schanz Screw is an external fixation component intended for use in the metacarpals to reduce and stabilize fractures of the hand and wrist.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_
(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002605